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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,691	05/08/2005	Jill Van Winkle	AG03-005C-US	3095
23500	7590	06/14/2006	EXAMINER KUMAR, VINOD	
PATENT DEPT EXELIXIS, INC. 170 HARBOR WAY P.O. BOX 511 SOUTH SAN FRANCISCO, CA 94083-0511			ART UNIT 1638	
DATE MAILED: 06/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,691	VAN WINKLE ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/03/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 are examined. All previous rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is suggested that "complementary" be amended to "fully complementary". Otherwise, it reads on a 2 mer sequence or a different sequence.

Claims 3, 4, 7 and 8 are rejected under 112, second paragraph as being indefinite in the recitation "non-modified", which is confusing, since it is unclear what type of modification is encompassed by the recitation. It is suggested to replace "non-modified" with --non-transgenic control--.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide a DRO2 polypeptide SEQ ID NO: 2, does not reasonably provide enablement for sequences which have less than 100% sequence identity to SEQ ID NO: 2, and the plants comprising said sequences for the reasons of record stated in Office action

mailed January 30, 2006. Applicants traverse the rejection in the paper filed May 3, 2006.

In the paper filed May 3, 2006, Applicants argue that specification provides guidance necessary to make and use the sequences encompassed in the claims. Applicants further argue that Doff DNA-binding domain is provided, including the consensus sequence for a zinc finger domain (response, page 7, lines 11-27).

Applicant's arguments were fully considered but were not persuasive. Applicants are reminded that neither the state of prior art nor the specification provide guidance on which region(s) of SEQ ID NO: 2 is able to tolerate deletions, additions or substitutions of one or more amino acid without abrogating drought tolerance function. The polynucleotide sequences encoding for a polypeptide with 95% sequence identity to SEQ ID NO: 2 would encompass sequences that do not have drought tolerance activity.

To further address Applicant's arguments, see for example, Guo et al. (PNAS, 101: 9205-9210, 2004) who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as the claims would encompass more than a single amino acid changes of the encoded protein when compared with SEQ ID NO: 2. Thus it is highly unpredictable that a nucleic acid sequence which is not 100% identical to SEQ ID NO: 2 would encode a polypeptide that has the ability to modify a response to stress. Undue experimentation is required by a skilled artisan to determine how a polypeptide which is less than 100% identical to SEQ ID NO: 2 would produce a drought tolerance phenotype when expressed in a transgenic plant.

Also breadth of claims encompass complementary sequence and sense strand having drought tolerance phenotype. Undue experimentation is required by a skilled artisan to determine how complementary strand can encode a polypeptide with drought tolerance property.

Accordingly, this rejection is maintained.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed January 30, 2006. Applicants traverse the rejection in the paper filed Applicants traverse the rejection in the paper filed May 3, 2006.

Applicants argue that description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that genus embraces. Further, Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention (response, page 8, lines 19-29).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that the specification does not have adequate written description for the genus of sequences which have at least 95% sequence identity to SEQ ID NO: 2, and one skilled in the art cannot reliably predict the structures based on nucleic acid sequence encoding SEQ ID NO: 2. The specification has failed to describe structures of the broadly claimed genus and correlate said structures to the function of drought

tolerance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP1033405, Published June 9, 2000).

Alexandrov et al. teach a method of producing a transgenic plant comprising a polynucleotide sequence encoding a polypeptide (SEQ ID NO: 33003) which is 100% identical to instant SEQ ID NO: 2. The reference teaches transforming a plant cell with an expression vector comprising said polynucleotide sequence operably linked to a promoter, obtaining transgenic plant and seed from the plant cell that expresses said polypeptide, or wherein said promoter is constitutive. See pages 341, 343, claims 1, 25, 29-34; page 326, paragraph 2279; page 327; page 329, paragraphs 2301-2308 of the reference. The property of drought tolerance of transgenic plant expressing said polynucleotide is inherent to the sequence taught in the reference.

Accordingly, Alexandrov et al. anticipate the claimed invention.

Summary


6. No claims are allowed. Harper et al. (US Patent Publication No. 20020160378, filed August 24, 2001; US Patent Publication No. 20040009476, filed August 24, 2001; WO200216655 A2, Published February 28, 2002) teach a nucleic encoding a polypeptide which has 100% sequence identity to instant SEQ ID NO: 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vinod Kumar
June 8, 2006


PHUONG T. BUI
PRIMARY EXAMINER 6/8/06